

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT : Jackowski et al.
INVENTION : **Apolipoprotein Biopolymer Markers
Indicative of Insulin Resistance**
SERIAL NUMBER : 09/993,366
FILING DATE : November 21, 2001
EXAMINER : Davis, Deborah A.
GROUP ART UNIT : 1655
OUR FILE NO. : 2132.101

Mail Stop: Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR § 1.132

I, Ferris H. Lander, do hereby declare as follows:

1. I am a registered Patent Agent and am authorized to represent the inventor's and assignee in the application entitled **"Apolipoprotein Biopolymer Markers Indicative of Insulin Resistance"**, having U.S. Application Serial No. 09/993,366, filed November 21, 2001.

2. In the Office Action mailed on August 8, 2006, claims 1 and 39-46 (as presented on July 12, 2005) were rejected under 35 USC 101 because the claimed invention allegedly is drawn to an invention that is not supported by either a substantial, credible or a well-established utility. Claims 1 and 39-46 were also

rejected under 35 U.S.C. 112, first paragraph because since the claimed invention is not supported by either a substantial, credible or a well-established utility , one skilled in the art clearly would not know how to use the claimed invention.

Specifically, the Examiner asserts that the differential expression of SEQ ID NO:1 is not evident and thus, the data is ambiguous.

3. Applicants submit that Figures 1 and 2, as originally filed, are evidence of record which supports Applicants' assertion of the usefulness of the claimed biopolymer marker (SEQ ID NO:1) for diagnosis and/or treatment of insulin resistance. Figure 2 shows a mass spectral profile of a peptide obtained from Band 7 of the gel shown in Figure 1. This mass spectral profile is the characteristic mass spectral for the claimed biopolymer marker, a fragment of apolipoprotein A-IV precursor having a molecular weight of about 1312 daltons and identified as SEQ ID NO:1. As evidenced in Figure 1, the claimed biopolymer marker (SEQ ID NO:1) is differentially expressed in a disease state (insulin resistance/diabetes) as compared to a normal physiological state.

4. In order to further illustrate this differential expression, Applicants provide the attached figure entitled "HiQ 1-(Elution) Insulin Resistance vs. Normal" which represents Figure 1 as originally filed. The figure attached hereto was produced by scanning the original photograph of the gel taken at the time of the experiment. Expression of Band 7, from which the claimed peptide was identified, is shown in all of the samples obtained

from normal patients (lanes 7-9, as numbered from the left) and in one of the two samples obtained from patients having insulin resistance (lane 3). In contrast, expression of Band 7 was not found in any of the samples obtained from patients having diabetes (lanes 2, 5 and 6) or in one of the two samples obtained from patients having insulin resistance (lane 4). Thus, contrary to the Examiner's assertion, the differential expression of the claimed biopolymer marker (SEQ ID NO:1) is evident and non-ambiguous.

No new matter has been added; the figure attached hereto is simply a clearer copy of Figure 1 as originally filed and is provided to clarify the presence and differential expression of the claimed biopolymer marker (SEQ ID NO:1). The gel shown in the figure does not represent new experimentation; the figure shows only a clearer image of the original gel made at the time that the experiments described in the instant specification were first carried out.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

10/25/2006
Date

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Fig 1-(Elution) Insulin Resistance vs. Normal

